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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,322	04/05/2001	Laurent Schaller	6835-60067 (0800195-46)	5639

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,322

Applicant(s)

SCHALLER ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03 May 2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species III in the reply filed on April 28, 2004 is acknowledged. Claims 1-26 and 31-38 are under consideration. Claims 27-30 have been cancelled.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: element 1703. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-14, 20-23 and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. in US Patent No. 5,941,888.

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Regarding claim 1, Wallace et al. disclose a tissue connector assembly having a surgical fastener having two clips (such as 102, 104, etc) and a bridge portion (such as 106) connecting the two clips (such as 102, 104), as seen in figure 1.

Regarding claim 2, Wallace et al. disclose that as applied to claim 1, as well as, a bridge portion (such as 106) that is substantially straight, as seen in figure 1.

Regarding claim 3, Wallace et al. disclose that as applied to claim 2, as well as, two clips (such as 102, 104, etc.) that have an open configuration and a closed configuration, as discussed in column 5, lines 47-55.

Regarding claim 4, Wallace et al. disclose that as applied to claim 3, as well as, a bridge portion that provides a predetermined spacing between the clips in the closed configuration, as discussed throughout the specification and seen in figure 1.

Regarding claim 5, Wallace et al. disclose that as applied to claim 3, as well as, at least one of the two clips (such as 102, 104, etc.) that is a self-closing clip, as recited in column 5, lines 47-55.

Regarding claim 6, Wallace et al. disclose that as applied to claim 5, as well as, a self closing clip that includes a shape memory material, as recited in column 5, lines 47-55.

Regarding claim 7, Wallace et al. disclose that as applied to claim 5, as well as, a coil (such as 102, 104) surrounding a substantial length of the self-closing clip (such as 102, 104).

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Regarding claim 8, Wallace et al. disclose that as applied to claim 5, as well as, a closed configuration that is an unbiased configuration, as discussed in column 5, lines 47-55.

Regarding claim 9, Wallace et al. disclose that as applied to claim 5, a closed configuration is a loop, as seen in figure 5.

Regarding claim 10, Wallace et al. disclose that as applied to claim 5, as well as, an open configuration that is a biased configuration, and further having a release mechanism (such as a catheter) having a first position to bias the self-closing clip in the open configuration.

Regarding claim 11, Wallace et al. disclose that as applied to claim 10, as well as, a closed configuration is an unbiased configuration, and wherein the release mechanism (such as a catheter) has a second position (via a pusher as described in US 4,994,069) to unbias the self-closing clip into the closed configuration.

Regarding claim 12, Wallace et al. disclose that as applied to claim 11, as well as, a coil (such as 102, 104) surrounding a substantial length of the self-closing clip, where the coil is coupled at one point on the self-closing clip and releasably coupled via the release mechanism at a second point on said self-closing clip.

Regarding claim 13, Wallace et al. disclose that as applied to claim 12, as well as, a first position that provides for compressing the coil between said first point and second point to form said biased configuration, via the deployment method.

Regarding claim 14, Wallace et al. disclose that as applied to claim 13, as well as, a second position that provides for releasably uncoupling the coil from said second point to form said unbiased configuration.

Regarding claim 20, Wallace et al. disclose a tissue connector assembly having a surgical fastener with two clips (such as 102, 104) including at least one self-closing clip having an open configuration and a closed configuration, where the open configuration is a biased configuration and the closed configuration is an unbiased configuration, and a bridge portion (such as 106) having a substantially straight portion connecting the two clip and a release mechanism (such as a catheter) having a first position to bias said self-closing clip in the open configuration, and a second position to unbias said self-closing clip into said closed configuration, as recited throughout the specification and seen in figures 1 and 5.

Regarding claim 21, Wallace et al. disclose that as applied to claim 20, as well as, a coil (such as 102, 104) surrounding a substantial length of said self-closing clip, where the coil is coupled at one point on the self-closing clip and releasably coupled via the release mechanism at a second point on the self-closing clip.

Regarding claim 22, Wallace et al. disclose that as applied to claim 21, as well as, a first position that provides for compressing said coil between the first point and second point to form the biased configuration.

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Regarding claim 23, Wallace et al. disclose that as applied to claim 22, as well as, a second position that provides for releasably uncoupling the coil from the second point to form said unbiased configuration, via the deployment method.

Regarding claim 31, Wallace et al. disclose a surgical clip apparatus having an elongated member, a pair of coils (such as 102, 104) surrounding at least a portion of the elongated member where the pair of coils are serially arranged and spaced from one another along the elongated member, as seen in figure 1. The elongated member is made of shape memory material and has an unbiased shape that includes a plurality of loops and a biased shape. The elongated member tends to move toward the unbiased shape to form the biased shape, as discussed in column 5 and seen in figures 1 and 5.

Regarding claim 32, Wallace et al. disclose that as applied to claim 31, as well as, loops that are spaced from one another, as seen in figures 1 and 5

Regarding claim 33, Wallace et al. disclose that as applied to claim 32, as well as, each coil that surrounds at least a portion of a different one of the loops.

Regarding claim 34, Wallace et al. disclose that as applied to claim 31, as well as, each coil that has an outer end and an inner end and the inner ends are spaced from one another, as seen in figures 1 and 5.

Regarding claim 35, Wallace et al. disclose that as applied to claim 32, as well as, each coil that has an outer end and an inner end and the elongated member has two enlarged portions,

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further including a restraint (such as 106) coupled to the elongated member adjacent to each of the inner ends, as seen in figure 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 15-19, 24-26 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al. in US Patent No. 5,645,568.

Regarding claim 15, Chervitz et al. disclose a tissue connector assembly having a surgical fastener with two clips and a bridge connecting the two clips and two ends including a first end and a second end, and further having two tissue piercing members (12) including a first tissue piercing member releasably coupled (can be cut/detached) to the first end and a second tissue piercing member releasably coupled to the second end. However, Chervitz et al. do not recite at least one of the two clips that is a self-closing clip. On the other hand, it would be obvious to one with ordinary skill in the art to provide the system with self-closing clipping for the purpose of enhanced attachment.

Regarding claim 16, Chervitz et al. as modified disclose that as applied to claim 15. Further, a release mechanism, that activates the release of said two piercing members from said respective two ends would be obvious to one with ordinary skill in the art, for it has been held that to make something separable involves only routine skill in the art.

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Regarding claim 17, Chervitz et al. as modified disclose that as applied to claim 16. Further, a release mechanism that activates the closing of said self-closing clip would be obvious given the combination.

Regarding claim 18, Chervitz et al. as modified disclose that as applied to claim 15, as well as, a suture, wherein the coupling of the first tissue-piercing member to the first end includes suture, and wherein the coupling of the second tissue-piercing member to the second end includes suture.

Regarding claim 19, Chervitz et al. as modified disclose that as applied to claim 18, as well as a suture of the first coupling and said suture of the second coupling are between about 10 mm and about 300 mm in length.

Regarding claim 24, Chervitz et al. disclose a tissue connector assembly having a surgical fastener having two ends including a first end and a second end and including two clips (via 10 and 11), and a substantially straight bridge portion (such as 13) connecting the two clips; and two tissue piercing members (12) including a first tissue piercing member releasably coupled to the first end and a second tissue piercing member releasably coupled to said second end. However, at least one self-closing clip has not been recited. On the other hand, it would be obvious to one with ordinary skill in the art to provide the system with self-closing clipping for the purpose of enhanced attachment.

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Regarding claim 25, Chervitz et al. as modified disclose that as applied to claim 24. Further, a release mechanism that activates the release of the two piercing members from the respective two ends would be obvious to one with ordinary skill in the art, for it has been held that to make something separable involves only routine skill in the art.

Regarding claim 26, Chervitz et al. as modified disclose that as applied to claim 25. Further, a release mechanism that activates the closing of said self-closing clip would be obvious given the modification.

Regarding claim 36, Chervitz et al. disclose a tissue connector apparatus having a surgical clip with first and second piercing members (12) each having first and second end portions, first and second couplings and first and second flexible members (11). The clip has first and second end portion where the first coupling is coupled to the first end portion of the clip and the second coupling is coupled to the second end portion of the clip where the first flexible member has a first end portion coupled to the first coupling and a second end portion secured to the second end portion of the first tissue piercing member the second flexible member has a first end portion coupled to the second coupling and a second end portion secured to the second end portion of the second tissue piercing member. However, Chervitz et al. do not recite an elongated member, a pair of coils surrounding at least a portion of the elongated member where the pair of coils are serially arranged and spaced from one another along the elongated member, the elongated member being shape member material and having an unbiased shape that includes a plurality of loops and a biased shape. The elongated member tends to move toward the unbiased shape from the biased shape. On the other hand, it would be obvious to

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one with ordinary skill in the art to provide the system with self-closing clipping for the purpose of enhanced attachment.

Regarding claim 37, Chervitz et al. as modified disclose that as applied to claim 36. Further, a first coupling releasably coupled in the first end portion of the surgical slip to the first needle would be obvious to one with ordinary skill in the art, for it has been held to make something separable involves only routine skill in the art.

Regarding claim 38, Chervitz et al. as modified disclose that as applied to claim 37. Further, a second coupling couples the second end portion of the clip to a second needle would be obvious to one with ordinary skill in the art, for it has been held to make something separable involves only routine skill in the art.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-26 and 31-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 09/828,335. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because they are merely reworded representations for the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 31-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 8, 41, 45, and 46 of U.S. Patent No. 6,641,593. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

11. Claims 31-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 34, 55-57, 61 and 91-93 of U.S. Patent No. 6,613,059. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

Conclusion

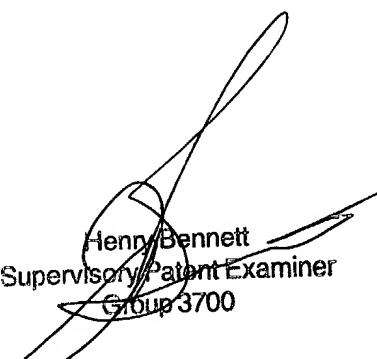
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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